DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–5347]

Draft "Guidance for Industry: Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products From Xenotransplantation Product Recipients and Their Contacts;" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled "Guidance for Industry: Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products From Xenotransplantation Product Recipients and Their Contacts." The draft guidance document is intended to provide recommendations to all registered blood and plasma establishments, and establishments engaged in manufacturing plasma derivatives. The draft guidance document provides recommendations regarding donor deferral and the disposition of blood products.

DATES: Submit written comments at any time, however, comments should be submitted by [insert ***date 60 days after date of publication in the*** **Federal Register],** to ensure their adequate consideration in preparation of the final document.

ADDRESSES: Submit written requests for single copies of "Guidance for Industry: Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products From Xenotransplantation Product Recipients and Their Contacts'' to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document

may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800, or by fax by calling the FAX Information System at 1-888-CBER-FAX or 301-827-3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document. Submit written comments on the draft guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance document entitled "Guidance for Industry: Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products From Xenotransplantation Product Recipients and Their Contacts." The draft guidance document provides FDA's recommendations to all registered blood and plasma establishments and establishments engaged in manufacturing plasma derivatives regarding donor deferral. It also provides recommendations on the disposition of blood products manufactured from a donor who is retrospectively discovered to have received a xenotransplantation product or to have been in close contact with a recipient of a xenotransplantation product.

Concerns have arisen in the last few years about the potential infectious disease and public health risks associated with xenotransplantation. Zoonoses are infectious diseases of animals that can be transmitted to humans through exposure to, or consumption of animals. Because transplantation necessitates disruption of the recipient's usual protective physical and immunologic barriers, xenotransplantation may facilitate transmission of known or as yet unrecognized infectious agents to humans.

The "Draft Public Health Service (PHS) Guideline on Infectious Disease Issues in Xenotransplantation" published in the **Federal Register** of September 23, 1996 (61 FR 49920). The draft guideline, which includes outlines of health surveillance programs and principles for screening candidate source animals for infectious agents of concern, indicated that patient consent forms should state clearly that xenotransplantation product recipients should never, subsequent to receiving the transplant, donate Whole Blood, blood components, Source Plasma, Source Leukocytes, tissues, breast milk, ova, sperm, or any other body parts for use in humans.

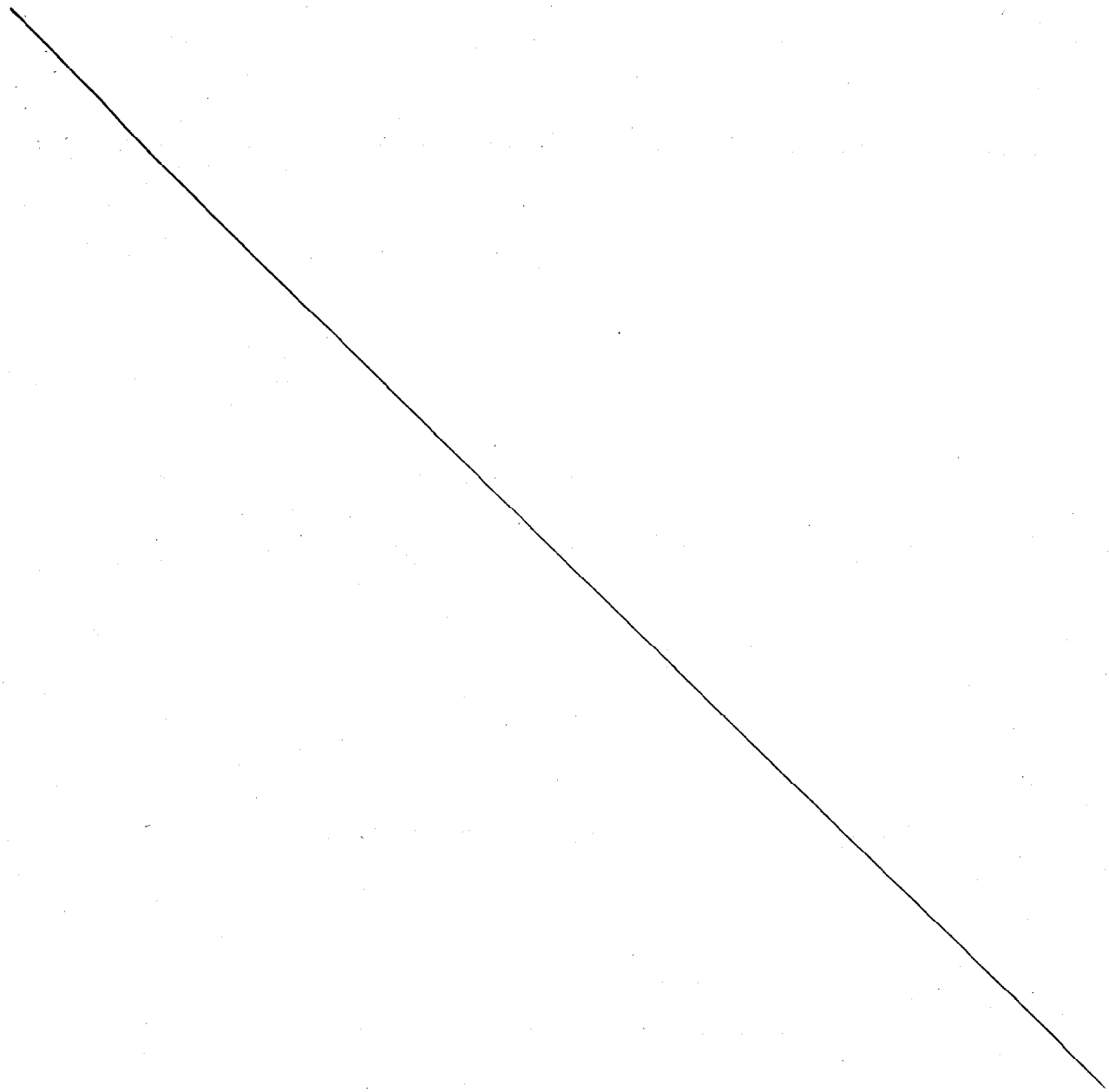
In an open public meeting on December 17, 1997 (62 FR 62776, November 25, 1997), the Xenotransplantation Subcommittee of the Biological Response Modifiers Advisory Committee recommended that close contacts of xenotransplantation product recipients, as well as the recipients themselves, should not donate blood or tissue because these individuals are theoretically at risk of acquiring zoonoses, and of transmitting them through blood and tissue donations. At FDA's Blood Products Advisory Committee open public meeting held on March 19, 1998 (63 FR 8461, February 19, 1998), donor deferral issues related to xenotransplantation were also discussed.

The draft guidance document represents the agency's current thinking with regard to possible risk of transmission of zoonoses by xenotransplantation product recipients and their contacts, through blood and blood products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statute, regulations, or both. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

The draft guidance document is being distributed for comment, however, the recommendations may be implemented immediately without prior approval by FDA. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance

document. Written comments may be submitted at any time, however, comments should be submitted by *[insert date 60 days after date of publication in the* **Federal Register],** to ensure adequate consideration in preparation of the final document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the draft guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.



III. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/cber/guidelines.htm.

Dated: 12/22/99
December 22, 1999

Margaret M. Dotzel
Acting Associate Commissioner for Policy

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